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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,772	09/22/2003	Phillip A. Patten	0103.12D-US	1379

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EXAMINER

VOGEL, NANCY S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/667,772	Applicant(s) PATTEN ET AL.	
	Examiner Nancy T. Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-14 are pending in the case.

It is noted that the information regarding priority included in the first page of the specification differs from that found on the application data sheet, filed 9/22/03.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-4 in the reply filed on 6/6/05 is acknowledged.

It is noted that applicants have cancelled the claim of the non-elected Group II, i.e. claim 15.

Sequence compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the specification and drawings that lack sequence identifiers. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 244.02). If the sequences are already present in the sequence listing, it would be remedial to amend the Brief Description of the Drawings and the specification to include the appropriate sequence identifiers. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these

requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F. R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

Claim Objections

Claim 7 is objected to because of the following informalities: the claims recites "[t]he method of step 6", when presumably "claim 6" is intended. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and by dependence claims 2-14 are vague and indefinite in being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP 2172.01. The claims are drawn to a "method for evolving a protein" but fail to recite any method step in which a protein per se is involved. It is suggested to clarify by reciting steps for evolving the protein.

Claims 5 and 8 are vague and indefinite in the recitation of the term "[t]he method of claim 1, where the DNA substrate molecule..." (claim 5), and "wherein the DNA

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substrate molecule..." (claim 8), since it there are 2 DNA substrate molecules recited in claim 1, i.e. a first and second DNA substrate molecule, and it is not known which is being referred to. Therefore the intended metes and bounds of the claim are unclear.

Claim 6 and by dependence claims 7-9 are vague and indefinite in the recitation of "[t]he method of claim 1, wherein at least one restriction endonuclease fragment from **a DNA substrate molecule** is isolated..." [emphasis added] since it is not clear whether the recited DNA substrate molecule is one of the first and second DNA substrate molecules recited in claim 1, and if so, which is intended.

Claim 12 is vague and indefinite in the recitation of "the products of (d) are used as a DNA substrate molecule in (b)". First, the result of (d) is a product (singular), not "products" as recited in claim 12. Second, it is not clear how the product of part (d), which is "a recombinant DNA substrate molecule encoding an evolved protein" can be used as a DNA substrate molecule in step (b), since step (b) recites "ligating the mixture to generate a library of recombinant DNA molecules". The "mixture" is a restriction enzyme digested first and second DNA substrate molecule. Therefore it is not clear how the product of (d) could be used in (b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,335,160. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued patent US 6,335,160 are drawn to the same method steps, except that in part (a) of claim 1, the first and second DNA substrate are "homologous and differ from each other in at least one nucleotide...wherein the at least first and second DNA substrate molecules each encode a protein, or are homologous to a protein-encoding DNA substrate molecule", and there is an additional step (e) in which the steps a-d are repeated, while the instant claims recite that the first and second DNA substrate molecules "differ from each other in at least one nucleotide". The claims drawn to a method comprising a step using a first and second DNA substrate with homology, and which differ by at least one nucleotide, and which have protein encoding properties, anticipate the broader genus claims of the instant application since said genus claims fully encompass the species claimed in the patent. Repeating the steps (a) – (d) would have been obvious to one of skill in the art since the claim is drawn to a method using any first and second DNA substrate molecule, and the product of the method steps (a) – (d) would have been an obvious DNA substrate to use in the method and is therefore encompassed by the

claims of the patent. Furthermore, the additional step of repeating the method steps is recited in claim 4 of the instant patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber et al. (Nucl. Acids Research, 11, (16): 5661-5669, 1983).

Weber disclose a method for evolving a protein encoded by a DNA substrate molecule, comprising digesting at least a first and second DNA substrate molecule with a restriction endonuclease, ligating the mixture to generate a library of recombinant DNA molecules, screening or selecting the products of (b) for a desired property, and recovering a recombinant DNA substrate molecule encoding an evolved protein (see Fig. 1, see page 5665 first complete paragraph – page 5668).

Claims 1-3, 6-8, 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Adey et al. (Phage Display of Peptides and Proteins, Academic Press, 277-291, 1996).

Adey et al. disclose a method of evolving a protein comprising digesting a first and second DNA substrate with a restriction endonuclease having non-palindromic ends at cleavage sites, ligating the mixture to generate a library of recombinant DNA molecules, screening or selecting the products of (b) for a desired property, and

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recovering a recombinant DNA substrate molecule encoding an evolved protein (see Fig. 5, C).

Claims 1-3, 6, 7 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowman et al. (J. Mol. Biol., 234, 564-578, 1993).

Lowman et al. disclose a method of evolving a protein comprising digesting at least a first and second DNA substrate molecule wherein they differ from each other in at least one nucleotide with a restriction endonuclease that has non-palindromic ends at cleavage sites (ie SfiI), ligating the mixture to generate a library of recombinant DNA molecules, and screening or selecting the products and recombining a recombinant DNA substrate molecule encoding an evolved protein (see page 566, second column, part (b); first paragraph, Fig. 2, page 568-569).

Conclusion

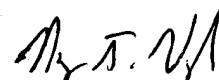
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NANCY VOGEL, PH.D.
PATENT EXAMINER